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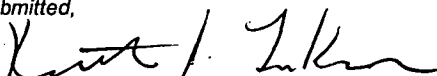
PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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Phillip J.	Davis	Belleville, New Jersey			
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max) INTRAURETHRAL MAGNETIC VALVE AND METHOD AND TOOL FOR IMPLANTING, EXTRACTING, AND MANIPULATING SAID VALVE IN THE URETHRA					
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ENCLOSED APPLICATION PARTS (check all that apply)					
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Respectfully submitted,

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Invention: **INTRAURETHRAL MAGNETIC VALVE AND METHOD AND TOOL FOR IMPLANTING, EXTRACTING, AND MANIPULATING SAID VALVE IN THE URETHRA**

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U.S. PROVISIONAL PATENT APPLICATION

INTRAURETHRAL MAGNETIC VALVE AND METHOD AND TOOL
FOR IMPLANTING, EXTRACTING, AND MANIPULATING SAID VALVE
IN THE URETHRA

Abstract and Summary

An intraurethral magnetic valve for insertion into the urethra of a person's body is provided to selectively provide fluid discharge therefrom and to spontaneously provide high-pressure relief. The intraurethral magnetic valve has a housing with a cylindrical wall and first and second ends each with an aperture. Within the housing is a nonferromagnetic fixed valve seat, a movable ferromagnetic valve seat between the fixed valve seat and the housing's second end, a valve element containing a cylindrical permanent magnet between the fixed valve seat and the housing's first end, a compression spring between the movable valve seat and the housing's second end, and a retaining ring at the housing's first end for retaining the valve element while allowing universal movement of the valve element in the housing in response to an external magnet. The fixed and movable valve seats are normally held in sealing engagement with each other by the compression spring, but responsive to hydrostatic pressure in the urethra can move from each other thereby providing spontaneous fluid discharge via the housing. The housing may be installed in a stent implantable in the urethra. About the aperture at the second end of the housing are two flanges for engaging a tool for implanting, extracting, manipulating and/or irrigating the intraurethral magnetic valve within the urethra of a person's body. Such tool may be used with other valves or devices which are provided with such flanges for engaging the tool. Further, the housing with cylindrical wall and apertured end with such flanges may be used without the valve components in other applications.

U.S. PROVISIONAL PATENT APPLICATION

INTRAURETHRAL MAGNETIC VALVE AND METHOD AND TOOL
FOR IMPLANTING, EXTRACTING, AND MANIPULATING SAID VALVE
IN THE URETHRA

FIELD OF THE INVENTION

The present invention relates to an intraurethral magnetic valve, and particularly to an intraurethral magnetic valve for insertion into the urethra of a person's body to selectively provide fluid discharge therefrom and to spontaneously provide high-pressure relief. The invention further relates to a method and tool for implanting, extracting, manipulating and irrigating the intraurethral magnetic valve within the urethra of a person's body. Such tool may be used with other valves or devices adapted for engaging the tool.

BACKGROUND OF THE INVENTION

Devices for implanting and removing intraurethral sphincter prostheses for treatment of urinary retention have been developed using devices for detecting, gripping and positioning valves and stents within the urethra, as described in U.S. Patent Nos. 3,642,004, 5,041,092 and 5,112,306 or use multilumen devices for inflating and deflating stent fixating balloons, as described in U.S. Patent No. 5,964,732. Also developed have been separate tools for insertion and extraction, and tethers for retrieval of valves and stents, as described, for example, in 6,551,304. These devices for implanting and removal of intraurethral devices are complex and do not provide immediate confirmation of proper placement in the urethra. Such immediate confirmation is desirable to avoid possible patient complications due to misplacement, or additional procedures to replace the prosthesis. Further, often these devices lack means to irrigate and cleanse intraurethral valves and stents, which can become fouled with renal calculus and tissue debris, and also do not provide needed accommodation for gross misalignment caused by bends and anatomical structures within the urethra to assure trauma free engagement with stent or valve during extraction.

Conventional intraurethral sphincter prostheses for treatment of urinary retention have used the interaction of internal and external magnets to open and close valves variously fixed

within the urethra either surgically or within stents, catheters or urethral plugs. These magnetic interactions have generally displaced a valve check along a straight two dimensional path to permit fluid flow, see for example, U.S. Patent Nos. 3,642,004, 3,812,841, 5,030,199, and 6,632,421. Additionally U.S. Patent No. 6,527,702 shows the use of the magnetic interaction indirectly by inflating or deflating a closure mechanism or to rotate threaded valve stems or keyed journals, see also U.S. Patent Nos. 6,221,060 and 6,417,750.

U.S. Patent Nos. 5,366,506 and 6,066,088 issued to the present inventor, permit the valve check to move in an arbitrary, three dimensional path. This free movement reduces friction effects and permits construction with few parts and simple geometric shapes. It also permits great flexibility and inaccuracy in the positioning of external actuating magnets and long working distances for those actuators. This flexibility enables an implant recipient having limited manual dexterity due to spinal cord injury or other neurological impairment to successfully operate the valve with a hand held switching magnet. In U.S. Patent No. 5,366,506 however, this freedom of check movement may restrict valve aperture diameter and thus can limit flow rates. Additionally, the freedom of movement prevents inclusion of a high-pressure relief mechanism.

SUMMARY OF THE INVENTION

One object of the present invention is to provide a valve housing and insertion/extraction tool which, when combined, provide simple placement and manipulation of valves, stents and valved stents in the human urethra, and which are highly tolerant of misalignment of valve and insertion/extraction tool, and provide for irrigating and cleansing intraurethral valves, stents and valved stents.

Another object of the present invention is to provide improvement of the flow rate of the valve described in U.S. Patent No. 5,366,506, by reducing drag at its inlet aperture and valve seat.

It is a further object of the present invention to improve U.S. Patent No. 5,366,506 to provide for high-pressure relief in the event of medically dangerous intravesical pressures.

Briefly described, the intraurethral magnetic valve embodying the present invention includes a nonferromagnetic cylindrical housing having inlet and outlet ends, a nonferromagnetic valve seat sealingly attached to the inner wall of the housing between the inlet and outlet ends, a

cylindrical valve element disposed for universal movement within the housing between the nonferromagnetic valve seat and the inlet end of the housing containing a high coercivity permanent magnet, a ferromagnetic valve seat disposed for axial movement within the housing between the nonferromagnetic valve seat and the outlet end of the housing, a compression spring disposed to maintain the ferromagnetic seat in contact with the nonferromagnetic seat, a retaining ring at the inlet end of the housing for maintaining the valve element within the housing, and a pair of flanges at the outlet end of the housing for maintaining compression on the spring. The flanges at the outlet end of the housing may be used for engaging an insertion/extraction tool to implant and remove the valve from the urethra.

The ferromagnetic valve seat is free to move axially away from contact with the nonferromagnetic seat by additional compression of the spring in response to high fluid pressure. This movement breaks the fluid seal between ferromagnetic and nonferromagnetic seats and permits fluid to escape through gaps between the ferromagnetic seat and housing, relieving medically dangerous excess intravesical pressure without intervention by an operator.

The nonferromagnetic valve seat has a sloping inner wall with a plurality of flanges which guide the freely moving valve check to concentric alignment with the ferromagnetic seat when in the normally closed position. By returning the check to this central position when closed, it is possible to maximize seat aperture diameter and thus maximize flow rate when open. U.S. Patent No. 5,366,506 allowed an arbitrary alignment when closed, requiring a reduction in aperture diameter to accommodate all possible closure positions and further prohibiting inclusion of a high-pressure relief mechanism. The present invention retains the U.S. Patent No. 5,366,506 omnidirectionality of valve opening in response to an external hand held magnet while maximizing aperture diameter and providing high-pressure relief. U.S. Patent No. 6,066,088, describes a spherical valve check and concave valve seat which are by nature self centering. The spherical check cannot contact and thus can not be held open by the pressure relief nonferromagnetic valve seat of that design permitting that design to be simpler and without the guide flanges of the present invention.

In response to a hand held or other external switching magnet, the cylindrical valve element moves arbitrarily within the confines of the housing, inlet end retaining ring, and combined ferromagnetic and nonferromagnetic seats, opening the valve to fluid flow. The gross dimensions of this confining space are selected so that at all possible open positions the sum of

friction forces at the contact points of valve element and both ferromagnetic and nonferromagnetic seats is not sufficient to hold the valve open on removal of the switch magnet.

The present invention is further directed to improvements in U.S. Patent Nos. 5,366,506 and 6,066,088 to provide improved manipulating means and to simplify stent design. U.S. Patent No. 5,366,506 provides a single chamber within the housing to hold the valve element and to receive an insertion/extraction tool. As the valve element travel is limited to a few tenths of millimeters, which space is shared with the insertion/extraction tool, that tool is required to have a thin planar face. A planar tip can only enter and engage the flanged housing if perfectly aligned with that housing. The nonferromagnetic frustoconical, two-flanged tip of the present invention can locate and guide itself into the present housing despite gross misalignment. The housing of the present invention has an additional chamber space within the valve providing room for the frustoconical tip independent of the valve element travel-limiting chamber of U.S. Patent No. 5,366,506. Other valves may be placed in the housing of the present invention leaving a similar additional chamber for the frustoconical tool. U.S. Patent No. 6,066,088 provides for the use of an insertion/extraction tool that engages soft, elastomeric material of stent end flanges rather than valve end flanges. The present invention improves U.S. Patent No. 6,066,088 by permitting the insertion/extraction tool to engage the valve housing enabling higher force levels needed for difficult intraurethral manipulations and eliminating the stent end flanges.

As an alternative embodiment, separate insertion and extraction tools may be provided having nonferromagnetic and ferromagnetic frustoconical tips, respectively. During extraction, the ferromagnetically tipped extraction tool would be used to draw to centered alignment with the valve housing by attraction to the magnetic valve element. The insertion tool has a nonferromagnetic tip to assure free disengagement from the valve during implantation. Or, a single insertion/extraction tool may be used with two replaceable tips, one ferromagnetic for extraction, and the other nonferromagnetic for implantation.

The housing of the present invention includes a nonferromagnetic biocompatible cylindrical tube of sufficient diameter to contain valve elements within and of sufficient strength and rigidity to hold those elements in fixed relationship to each other. Integral to the housing are a pair of flanges at the outlet end shaped to make loose fitting engagement with an insertion/extraction tool used to implant and remove devices from the urethra. The flanges are further shaped to mate with the above mentioned insertion/extraction tool despite gross

misalignment and to engage with the tool after minimal tool rotation. The housing flanges and the engagement flanges of the insertion/extraction tool interfere with each other, and do not to provide friction fit, threaded fit, or fluid seal. As such, they cannot jam or lock together making it impossible to separate the tool and valve within the urethra. Also, because they do not provide fluid seal, they can be used with any valve or stent to test urine flow during placement and manipulation. The present invention further includes, as an optional embodiment of the insertion/extraction tool, an elastomeric washer which provides an intentionally imperfect sealing member. Imperfect sealing permits valve irrigation at elevated pressure without risk of jamming tool and housing together.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing objects, features and advantages of the invention will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

Fig. 1 is a sectional view taken through the normally closed intraurethral magnetic valve in accordance with the present invention.

Fig. 2 is a sectional view through the valve of **Fig. 1** showing the path of fluid flow when open and with an arbitrary open position of the valve check shown in outline.

Fig. 3 is a sectional view through the valve of **Fig. 1** showing the path of fluid flow during high-pressure relief.

Figs. 4A and 4B are an inlet end view and sectional view, respectively, of the housing of the valve of **Fig. 1** showing outlet end flanges.

Figs. 5A and 5B are end and sectional views, respectively, of the nonferromagnetic high-pressure relief seat and valve check centering guide of the valve of **Fig. 1**.

Figs. 5C and 5D are end and sectional views, respectively, similar to **Figs. 5A and 5B** of an alternate embodiment of the high-pressure relief seat and valve check centering guide of the valve of **Fig. 1**.

Figs. 6A and 6B are an end and sectional view, respectively, of the ferromagnetic valve seat of the valve of **Fig. 1**.

Fig. 7 is a sectional view of the valve element assembly of the valve of **Fig. 1**.

Fig. 8 is a sectional view of the inlet retaining ring of the valve of **Fig. 1**.

Figs. 9A and 9B are end and side views of the tip of the insertion/extraction tool of **Fig. 9C** which may be used to engage the outlet end flanges of the valve of **Fig. 1**.

Fig. 9C is a schematic side view of the insertion/extraction tool having tip of **Figs. 9A and 9B** coupled in a length of catheter tubing.

Fig. 10A is an alternative embodiment of the tip in **Figs. 9A-9C**.

Figs. 10B and 10C are side views of the insertion/extraction tool tip of **Figs. 9A-9C** rotated 10 degrees and 90 degrees respectively.

Fig. 11A is a sectional view of the tip of **Fig. 10B**.

Fig. 11B shows the tip of **Fig. 11A** engaged in the housing of the valve of **Fig. 4A**.

Fig. 11C is a partial view of the insertion/extraction tool tip of **Figs. 9A-9C** entering the distal end of valve housing of **Fig. 1**, shown also in partial view, while grossly misaligned with the housing.

Fig. 12A is a schematic view of the valve of the **Fig. 1** secured in the distal end of an intraurethral stent and fully engaged with the insertion/extraction tool of **Figs. 9A-9C**.

Fig. 12B is a schematic view of insertion/extraction tool of **Figs. 9A-9C** in the stent and valve of U.S. Patent No. 6,066,088, said valve being adapted to receive and engage such tool.

Fig. 12C is a schematic view of the housing of **Fig. 1** secured in the distal end of an intraurethral stent in which no valve components of **Fig. 1** are provided therein.

Figs. 13A and 13B are end and sectional views respectively of a washer which may be used on the insertion/extraction tool of **Figs. 9A-9C** for increasing irrigation pressure of fluid delivered through the tool.

Fig. 13C is a side view of the irrigation washer of **Figs. 13A and 13B** affixed to the tool tip of **Figs. 9A-9C**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to **Fig. 1**, a valve assembly 1 shown in its normally closed position having a cylindrical nonferromagnetic housing 2 having a continuous sidewall 3. A ferromagnetic valve seat 4 of high magnetic permeability is sealingly held against a nonferromagnetic valve element guide 5 by compression spring 6. Valve element guide 5 is sealingly and fixedly held against housing sidewall 3. The valve element guide 5 is described in more detail later in connection with **Figs. 5A-5D**. A valve element assembly 7 is sealingly held against valve seat 4 by

magnetic attraction of magnet 8 to ferromagnetic seat 4. Valve element assembly 7 is described in more detail later in connection with Figs. 7. Nonferromagnetic retaining ring 9 limits movement of valve element assembly 7 when under the attraction of an external hand held magnet 50 shown later in Fig. 2. Retaining ring 9 has urine inlet aperture 10. Housing 2 flanges 11 maintain compression of spring 6 and engage an insertion/extraction tool 12 shown later in Figs. 9, 10, and 11. Housing distal end 2a has an aperture 13 defined by flanges 11 and sidewall 3 to permit urine to flow out of the valve and permit the insertion/extraction tool 12 to enter the valve. Spring 6 is made of, or plated with, biocompatible material and is positively compressed to provide sufficient bias force to resist displacement of seat 4 under the influence of normal and safe intravesical pressures at inlet aperture 10 when valve assembly 1 is installed in the urethra of a human patient.

Referring to Fig. 2, the valve assembly 1 is shown with valve element assembly 7 shown in outline in an arbitrary open position when under magnetic torque or attraction induced by external hand held magnet 50 (shown not to scale). The internal magnet 8 is normally attracted to ferromagnetic seat 4 causing the valve element to cover and occlude seat aperture 32. The external magnet 50 induces torque and attraction on the magnet 8 causing the valve element to tip away from seat 4 breaking the fluid seal between the valve element assembly 7 and the valve seat 4. Urine flow path is indicated by an arrow 100. To prevent jamming in an open position, the gross dimensions of valve element assembly 7 are chosen so that in all possible open positions a maximum of three contact points with other valve assembly elements are possible. These contacts may be: a rounded edge 17 of valve element 7 touching both valve seat 4 and guide 5 while a square edge 18 touches sidewall 3 or; square edge 18 touching retainer 9 and sidewall 3 while rounded edge 17 contacts sloping wall 19 of guide 5. In the general open position, there are only two contact points which are subsets of the above three point combinations. In all possible open positions the valve element and seat contact angles are limited so that the sum of friction forces on edge 17 tending to hold the valve open is less than the magnetic forces tending to spontaneously close the valve on withdrawal of the hand held switch magnet 50.

Referring to Fig. 3, valve assembly 1 is shown in the pressure relief position. Urine hydrostatic pressure at inlet 10 in excess of medically safe intravesical pressures overcomes spring 6 bias compression and displaces seat 4 from sealing engagement with the sealing face 14

of guide 5. Valve element assembly 7 displaces with seat 4. Urine then flows through the gap 15 between guide 5 and valve element assembly 7 and through gaps 16 between seat 4 and housing sidewall 3. Gaps 16 are shown in greater detail in Fig. 6A. Urine flow path is indicated by an arrow 101. Displacement of seat 4 and gaps 15 and 16 are shown exaggerated in Fig. 3 for purposes of illustration. Flow rate is low due to the narrow gaps, but sufficient to relieve bladder pressure.

Referring to Figs. 4A and 4B, two flanges 11 form crescents on the distal outlet end of valve housing 2. Generally circular arches 22 provide passageway for the generally conical tip of insertion/extraction tool 12 shown in detail in Figs. 9. Flat surfaces 23 act as rotational stops and engagements areas for tool 12 of Figs. 9. Groove 24 passing twice through housing sidewall 3 is optional and is merely a manufacturing convenience. Housing 2 is made of nonferromagnetic, biocompatible material.

Referring to Figs. 5A and 5B, guide ring 5 is shown with an opening 5a and a plurality of sloping tabs 25. Three or more tabs 25 are preferred. Their sloped surfaces 19 can contact valve element assembly 7 rounded edge 17 of Figs. 1 and 7 and guide that assembly to roughly concentric alignment with valve seat 4 of Fig. 1. By returning the valve element assembly to a central (or approximately central) position when closed, the valve seat 4 aperture 32 of Figs. 6, can be maximized resulting in maximized fluid flow rate. Ring 5 is cut down in areas 26 interleaved with tabs 25 to provide extra clearance for fluid flow around valve element assembly 7, further reducing drag and increasing flow rate. Surfaces 27 of interleaved areas 26 are relieved below surfaces 19 sufficiently to prevent contact of valve element assembly 7 with edges 28 which would prevent spontaneous valve closure. Surface 14 of guide ring 5 is sufficiently flat and smooth to form a noncompliant fluid seal with valve seat 4 at hydrostatic pressures normally found in the human bladder and under the bias contact force provided by spring 6 of Fig. 1. A compliant seal is an optional alternative embodiment. The outer surface of guide ring 5 has a diameter which frictionally engages the interior of wall 3 of housing 2. Guide ring 5 is made of nonferromagnetic, biocompatible material. However, other material less preferably may be used for housing 2 and ring 5 which may have low magnetic permeability.

Referring to Figs. 5C and 5D, an alternative embodiment of the guide ring 5 is shown lacking cut down areas 26 of Figs. 5A and 5B. This provides a guide ring 5 with an annular sloped interior surface about opening 5a of reducing diameter in the distal direction. This may

result in simplicity of manufacture, but at a slight reduction in flow rate.

Referring to **Figs. 6A and 6B**, the valve seat **4** of **Fig. 1** is shown. The seat is made of ferromagnetic material having high magnetic permeability and is made of, or plated with, biocompatible material. Surface **21** is sufficiently flat and smooth to form noncompliant fluid seals with valve element assembly **7** and guide **5** of **Fig. 1** at hydrostatic pressures normally found in the human bladder and under the bias contact force provided by spring **6** and magnetic attractive force provided by the valve element assembly. Compliant seals are optional alternative embodiments. Shoulders **29** fit loosely within housing sidewall **3** permitting axial movement of seat **4** away from guide **5**, breaking the seal between faces **21** & **14** and thus providing pressure relief as described earlier. Fluid flow is through narrow reliefs **16** between shoulders **29**. Depression **30** fixes compression spring **6** in concentric alignment with seat **4** as shown in **Fig. 1**. Bevel **31** on distal side of seat **4** reduces fluid drag through aperture **32**.

Referring to **Fig. 7**, the valve element assembly **7**, valve check, is shown in sectional view. Can **33** is generally cylindrical and made of nonferromagnetic, biocompatible material. Can **33** may represent a container with an open end through which a cylindrical permanent magnet **8** is received. The dimensions of the magnet **8** may be such that it fills or substantially fills the entire can but for a cap **36** received in the open end of can **33**. The cap may be held by adhesive, friction, or both in the can **33**. Surface **20** is sufficiently flat and smooth to form a noncompliant fluid seal with valve seat **4** of **Fig. 1** at hydrostatic pressures normally found in the human bladder and under the contact force provided by attraction of magnet **8** to valve seat **4**. Web **35** thickness is carefully controlled as in prior art to limit this attractive force. Cylindrical permanent magnet **8** is axially polarized with arbitrary polarity. Can **33** edge **17** is slightly rounded to prevent entanglement with scratches or machining imperfections in seat **4** and guide **5** and to assure consistent friction forces between the can **33** and those elements. Cap **36** may be of nonferromagnetic, biocompatible material and prevents contact of urine with magnet **8**. As an alternative embodiment, cap **36** and can **33** may be eliminated and the magnet **8** coated with biocompatible material sized to the dimension of can **33**.

Referring to **Fig. 8**, the retaining ring **9** of **Fig. 1** is shown in section view through its centerline with valve element assembly **7** shown in outline in a typical open position. The ring is made of nonferromagnetic, biocompatible material. The central aperture **38** diameter is limited so that at all possible open positions, edge **18** of valve element assembly **7**, cannot fall within

aperture 38, but must instead contact the ring on surface 39. Inlet side of aperture 38 has bevel 40 to reduce fluid drag.

Referring to **Figs. 9A, 9B and 9C**, the insertion/extraction tool 12 is shown. The tool 12 has at one end a tip 12a which is received into a catheter tubing 51. The tip 12a is made of nonferromagnetic biocompatible material. However, other biocompatible material may be less preferably used which have some ferromagnetic properties. For purposes of illustration, most rounding and filleting necessitated by machining practices or to prevent laceration of the urethra have been omitted from these figures. In practice, all corners and edges are preferably broken and smoothed. Tip 12a has at its frustoconical point 40 a lumen or opening 41, which extends from the frustoconical point 40 through the tip 12a and into tubing 51, to provide a path for urine flow through the entire length of the tip and a path for upstream irrigation as needed. Two flanges 42 emerge from cylindrical segment 43 terminating at their intersections with conical tip surface 44. Flanges 42 engage housing 2 flanges 11 of **Fig. 1**, and are used to pull on the valve assembly when extracting it from or positioning it in the urethra. Stop flanges 45 limit rotation of the tip 12a within housing 2 by interference with flanges 11 and transmit torque to rotate housing and stent 60 (see **Fig. 12A and 12C**, or **Fig. 12B** with respect to rotation of housing 109) within the urethra. Maximum tip rotation within housing 2 is less than 45 degrees. Shoulder 46 limits penetration of the tip into housing 2 and is used to push the valve into the urethra during implantation and positioning. Cylindrical segment 47 fits securely (by frictional engagement) in catheter tubing 51 shown sectioned and truncated in **Fig. 9C** which extends outside the body and is used to manipulate tip and engaged valve and may be used to irrigate the valve. Catheter tubing 51 may be of rubber, plastic, or other biocompatible material which can pass torque from one end of the tubing to the tip 12a at the other end of the tubing.

As an alternative embodiment, when tool 12 is used as an extraction tool, the tip 12a may be made of ferromagnetic material so that it is drawn to and aligned with the valve housing by magnetic attraction to the valve element. Two separate tools may be provided, a first tool with a ferromagnetic tip for extraction of the valve, and the second with a nonferromagnetic tip for implantation of the valve. Or, a single tool may be provided with replaceable ferromagnetic and nonferromagnetic tips 12a, which releasably engage (such as by friction) in the end of tubing 51, or these tips have detents or tabs along the outside of segment 47 which lock or latch into openings in tubing 51 when each tip is inserted in the tubing.

Referring to **Fig. 10A**, segment **47** of the tip shown in **Fig. 9B** may, as an alternative embodiment, be barbed with a plurality of barbs **48**, as shown to provide secure fixation within catheter tubing **51**.

Referring to **Figs. 10B** and **10C**, the tip **12a** of **Fig. 9B** is shown rotated 10 degrees and 90 degrees respectively to better show the outlines of engagement flanges **42** and stop flanges **45**. When the tool tip **12a** is engaged with a valve housing, as shown in **Fig. 11B**, engagement flanges **42** may be used to pull on the valve housing **2** by contact against flanges **11**. Similarly, when engaged, tip rotation within the housing is limited and torque transmitted to the housing by contact of surfaces **59** of stop flanges **45** against surfaces **23** of flanges **11**, providing means to rotate housing **2** and stent **60** (**Figs. 12A or 12C**), in which housing **2** is located (or housing **109** of **Fig. 12B**), within the urethra. In this manner, tip **12a** provides a key which may be inserted through opening **13** and rotated to lock tool **12** to housing **2** and facilitate placement by a physician or other trained person in the urethra of a patient, in which when the housing **2** is properly positioned in the urethra, reverse rotation unlocks the tool **12** which then can be removed through opening **13** and exit the urethra.

Referring now to **Figs. 11A**, for purposes of illustration, a sectional axial view of tip **12a**, **Fig. 10B**, is given rotated 30 degrees relative to the view in **Fig. 10B**. Further referring to **Fig. 11B**, the tip **12a** of **Fig. 11A** is shown in bold line fully engaged with housing **2** flanges **11**. In this position it can be used to push, pull and counterclockwise rotate the valve.

Referring to **Fig. 11C** a profile view **Fig. 10B**, of the tip **12a** is shown entering outlet aperture **13** of housing **2**, **Fig. 4**, shown here in outline, while grossly misaligned with the housing **2**. Tip conical surface **44** and housing aperture arches **22**, **Fig. 11B**, enable tip **12a** to locate and enter housing **2** despite severe misalignment. When used as an extraction tool within the urethra, tip **12a** must accommodate misalignment due to urethral bends and anatomical structures in order to locate and enter housing **2**. When used as an insertion tool, this misalignment capability permits severe bending around anatomical structures. After fully entering the housing, **Figs. 11B, 12A and 12B**, the tip is rotated less than 45 degrees to grip housing flanges **11** with tip flanges **42**. Rotation is accomplished by manually twisting the catheter tubing extension **51**, and rotation is limited by stop flanges **45**, **Fig. 10**. The catheter extension **51** is sufficiently long to provide extracorporeal gripping length and to facilitate hygienic disposal of urine drained through the tip lumen **41**, **Fig. 9A**, and catheter lumen **52**, **Fig.**

9C. Tip **12a** is disengaged from the valve by counter rotating until stop flanges **45** again interfere with housing flanges **11** and then extracted by pulling the catheter extension **51**.

Referring to **Fig. 12A**, the valve **1** of the present invention is shown in the distal end bulge **61** of a simplified malecot **62** tipped stent **60** having catheter segment **63** as described in U.S. Patent No. 6,066,088, and simplified by elimination of stent end flanges as discussed above and following. Insertion/extraction tool **12** is shown in outline, fully engaged with valve **1**. Catheter extension **51** is shown truncated for purposes of illustration.

Referring to **Fig. 12B**, the valve **71** and stent **60** of the U.S. Patent No. 6,066,088, are shown having a housing **109** having a spherical magnetic valve element **110**, fixed nonferromagnetic valve seat **111**, ferromagnetic ring **112**, and nonmagnetic retaining ring **113**, as described in U.S. Patent No. 6,066,088, which is herein incorporated by reference. The improvement being the space of gap **114** provided by the extension of housing **109** between ring **112** and an outlet port identical as at distal end **2a** of housing **2**, described earlier, with flanges **11**, such that the tip **12a** of tool **12** can engage the housing **109**. The outlet end of the valve is located at the distal end of stent bulge **60a**. In this manner, the insertion/extraction tool **12** can be used with the intraurethral magnetic valve of this patent to implant, extract, and manipulate the housing **109** in the urethra. (Such flange **11** may also be incorporated in spring retaining ring **135** in Figs. 5 and 6 of U.S. Patent No. 6,066,088, to similarly provide use with tool **12**). Similarly, the flanges **11** may be incorporated in other devices for placement of devices in a patient. Unlike U.S. Patent No. 6,066,088, the housing **2** of the present invention permits simplification of the stent, elimination of retaining ring **135** in Figs. 5 and 6 of U.S. Patent No. 6,066,088 in alternate pressure relief embodiments, and provides more robust gripping and manipulation means built into the valve independent of the stent. As a result, difficult urethral manipulations at higher force levels are possible and stent construction is simplified. Insertion/extraction tool **12** is shown fully engaged for manipulation of valve **71** and stent **60**. Catheter extension **51** is shown truncated for purposes of illustration. Valve **71** is secured in stent **60** by elastic tension of the stent rubber, adhesives, or both.

Referring to **Fig. 12C**, the housing **2** of the present invention is shown in the distal end of a typical stent without a valve. **Fig. 12C** illustrates that the housing **2** (or flanges **11** thereof) may be incorporated in other biocompatible device with or without a valve to facilitate use with tool **12**.

Referring to **Figs. 13A and 13B**, the irrigation pressure regulating washer **80** is shown in axial and sectional views respectively and affixed tip **12a** to the insertion/extraction tool **12** in **Fig. 13C**. The washer is made of biocompatible elastomeric material so that, when needed, it may be stretched over tip **12a** flanges **42** and clamp on cylindrical segment **43** and stop flanges **45** as shown in **Fig. 13C**. Hole **81** fits snugly around tip **12a** cylindrical segment **43** and slots **82** fit snugly to flanges **45**. Washer **80** is conical so that misaligned engagement of housing **2** and tip **12a** remains possible when washer **80** is installed. Washer **80** is thinner than the excess engagement space **66**, **Fig. 12A**, providing a loose fit between tip **12a** and housing **2**. As such, it will not jam tip and housing together and it will not entirely seal the gap between them. The washer will add significant fluid drag through gap **66**, effectively raising the pressure of irrigation water delivered through catheter lumen **51** and tip lumen **41**.

Although the above stent **60** is described, the valve assembly **1** may be placed in the distal end of other catheter stents and provide a remotely actuated valving function with high-pressure relief to those stents. Further, the housing **2** may be placed in stents, valved stents, and other appliances, and in conjunction with the tool **12** provide an effective means for placing and manipulating those devices within the urethra or other bodily lumen. Moreover, other valve apparatus than described herein may be placed in the housing **2** which may, in conjunction with the tool **12**, provide an effective means for placing and manipulating those valves within the urethra or other bodily lumen.

It will be apparent to those skilled in the art that the valve assembly **1**, housing **2**, and insertion/extraction tool **12** of the present invention can be used in other environments not exclusive to the human body or human urethra, such as other bodily lumen, not limited to humans or mammalian species, and fluid flow applications where placement of stemless, remotely controllable valves into piping is needed.

In summary, a simple valve housing and insertion/extraction tool have been described for gripping and manipulating stents, valves and valved stents to both implant and extract these from the urethra. Gripped stents or valves can be guided by palpation of the perineum and by tactile feedback of resistance and muscle tone from the external sphincter and other anatomical structures. The insertion/extraction tool provides immediate confirmation of proper stent placement at the bladder neck by permitting urine flow during placement, such as when used with U.S. Patent Nos. 5,366,506 and 6,066,088. The tool further permits irrigation and back

flushing. The housing and insertion tool are further capable of accommodating gross misalignment caused by bends and anatomical structures within the urethra, assuring trauma free engagement with stent or valve during extraction.

From the foregoing description, it will be apparent that there has been provided an improved intraurethral magnetic valve, housing, and insertion/extraction tool. Variations and modifications to the herein described valve, housing, and insertion/extraction tool in accordance with the invention will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.

What is claimed is:

1. An intraurethral magnetic valve for insertion into the urethra of a person's body to selectively provide fluid discharge therefrom and to spontaneously provide high-pressure relief therefrom, comprising:

a housing within which are disposed a fixed nonferromagnetic valve seat, a movable ferromagnetic valve seat, a valve element containing a cylindrical permanent magnet and disposed for universal movement within said housing, a compression spring, and a valve element retaining ring; and

said fixed and movable valve seats being normally held in sealing engagement with each other by said compression spring, but responsive to hydrostatic pressure to move from each other thereby providing spontaneous fluid discharge via said housing; and

said valve element being disposed for universal movement within said housing, but being guided by said nonferromagnetic fixed seat to central alignment with said ferromagnetic movable seat when in the normally closed position.

2. The intraurethral magnetic valve of claim 1 wherein said valve element is held in the normally closed position against said movable ferromagnetic seat by magnetic attraction to said seat

3. The intraurethral magnetic valve of claim 1 wherein said valve element has dimensions selected to enable in all possible open positions a maximum of three contact points with other valve elements.

4. The intraurethral magnetic valve of claim 1 wherein said fixed nonferromagnetic valve seat is sealingly attached within said housing.

5. The intraurethral magnetic valve of claim 1 wherein said fixed nonferromagnetic valve seat and said movable nonferromagnetic valve seat have planar surfaces sufficiently flat and smooth to form a noncompliant fluid seal with each other at contact forces provided by said spring and at hydrostatic forces safe for the human bladder.

6. The intraurethral magnetic valve of claim 1 wherein said fixed nonferromagnetic valve seat has a plurality of sloping surfaces tending to guide said valve element toward central axis alignment with said housing and said ferromagnetic valve seat.
7. The intraurethral magnetic valve of claim 1 wherein said fixed nonferromagnetic valve seat has a single sloping surface to guide said valve element toward central axis alignment with said housing and said ferromagnetic valve seat.
8. The intraurethral magnetic valve of claim 1 wherein said fixed nonferromagnetic valve seat has a plurality of sloping surfaces cut down and located below any possible contact with said valve element.
9. The intraurethral magnetic valve of claim 1 wherein said moving ferromagnetic valve seat is made of or plated with biocompatible material and has a distal side aperture bevel to reduce fluid drag.
10. The intraurethral magnetic valve of claim 1 wherein said movable ferromagnetic valve seat has a circular depression for concentric alignment with said compression spring.
11. The intraurethral magnetic valve of claim 1 wherein said movable ferromagnetic valve seat has a plurality of shoulders which tend to hold it in central alignment with said housing and provide space for fluid passage during high-pressure relief.
12. The intraurethral magnetic valve of claim 2 wherein said movable ferromagnetic valve seat and said magnetic valve element have planar surfaces sufficiently flat and smooth to form a noncompliant fluid seal with each other at contact forces provided by attraction of said permanent cylindrical magnet to said movable ferromagnetic seat and at fluid pressures normally found in the human bladder.
13. The intraurethral magnetic valve of claim 1 wherein said spring is made of or plated with biocompatible material.

14. The intraurethral magnetic valve of claim 1 wherein said retainer is made of nonferromagnetic biocompatible material and has an aperture inlet side bevel to reduce fluid drag.

15. The intraurethral magnetic valve of claim 14 wherein said valve element has edges and said retainer has an aperture diameter which limits possible positions of said valve element and prevents edge of said valve element from falling within said aperture.

16. A housing for valves, stents, valved stents and other apparatus intended for implantation in the human urethra or other bodily lumen, comprising:
a cylindrical wall having two ends each with apertures; and
one or more flanges at one of said ends for engaging a tool capable of manipulating said housing in one or more dimensions.

17. The housing of claim 16 being made of nonferromagnetic, biocompatible material.

18. The housing of claim 16 further comprising a movable ferromagnetic valve seat, wherein said flanges further comprise means for retaining a spring in compression and in concentric relationship with said ferromagnetic valve seat.

19. The housing of claim 16 wherein said flanges further comprise means for retaining a spring in compression and further comprising a movable ferromagnetic valve seat, and a depression in said seat maintaining said spring in concentric relationship with said ferromagnetic valve seat.

20. The housing of claim 16 wherein said flanges are two in number and disposed in axially symmetric relationship at said one end of said cylindrical wall.

21. The housing of claim 16 wherein said flanges are each crescent shaped.

22. The housing of claim **21** wherein said crescent shaped flanges each have concave arches to enable self centering of the tool when engaging said flanges.

23. The housing of claim **16** wherein said flanges having flat surfaces that interfere loosely with the tool when engaging said flanges.

24. The housing of claim **16** wherein said flanges are incapable of forming fluid seal with the tool when engaging said flanges.

25. A tool for implanting, extracting, manipulating and irrigating valves and other apparatus within the urethra of a person's body, comprising:

a tip having a frustoconical point, a lumen through its length, two flanges for pulling on apparatus, two rotational stop flanges for twisting apparatus and limiting tool rotation within apparatus, a shoulder flange for pushing apparatus, and a cylindrical segment for fixation to a length of catheter tubing having a central lumen, a length of catheter tubing, and a detachable washer.

26. The tool of claim **25** wherein said tip is nonmagnetic and biocompatible.

27. The tool of claim **25** wherein all said flanges engage said apparatus loosely by interference without friction, threaded fit or fluid seal.

28. The tool of claim **25** wherein said frustoconical point makes the tip self centering on said apparatus.

29. The tool of claim **25** wherein said stop flanges provide means for applying torque to said apparatus.

30. The tool of claim **25** wherein said stop flanges limit tip rotation within said apparatus to less than 45 degrees.

31. The tool of claim **25** wherein said cylindrical segment provides a fixation surface to a catheter tube of arbitrary length.

32. The tool of claim **25** wherein said catheter tube provides fixation to said tip by one of elastic tension or adhesion, or both tension and adhesion.

33. The tool of claim **25** wherein said pulling and stop flanges emerge from said frustoconical point.

34. The tool of claim **25** wherein said catheter tubing provides a conduit for bi-directional fluid flow.

35. The tool of claim **25** wherein said catheter tubing provides means for extracorporeal manipulation of said tip and said apparatus.

36. The tool of claim **25** wherein said washer is conical.

37. The tool of claim **25** wherein said washer is sufficiently thick to increase fluid drag at the connection of said tip to said apparatus, but insufficiently thick to block fluid leakage at said connection.

38. The tool of claim **31** wherein said cylindrical segment has a plurality of concentric barbs for secure fixation to said catheter tube.

39. The tool of claim **25** wherein said tip is ferromagnetic and biocompatible when said tool is used as an extraction tool.

Fig. 1

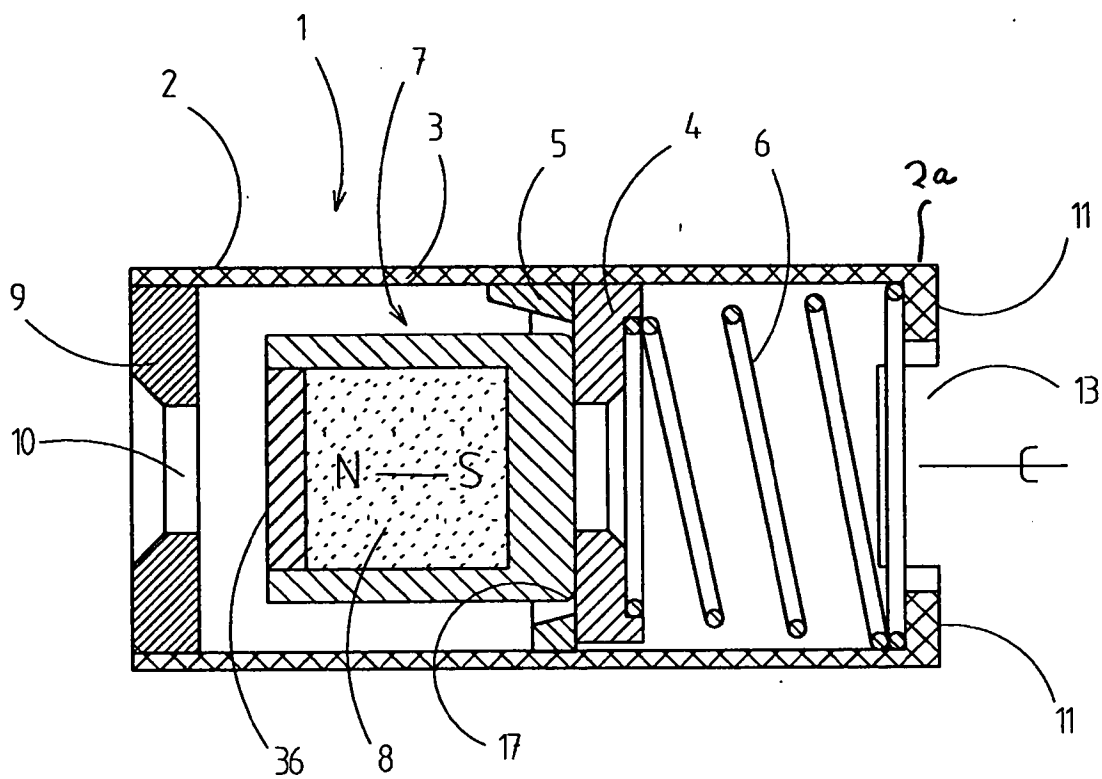


Fig. 2

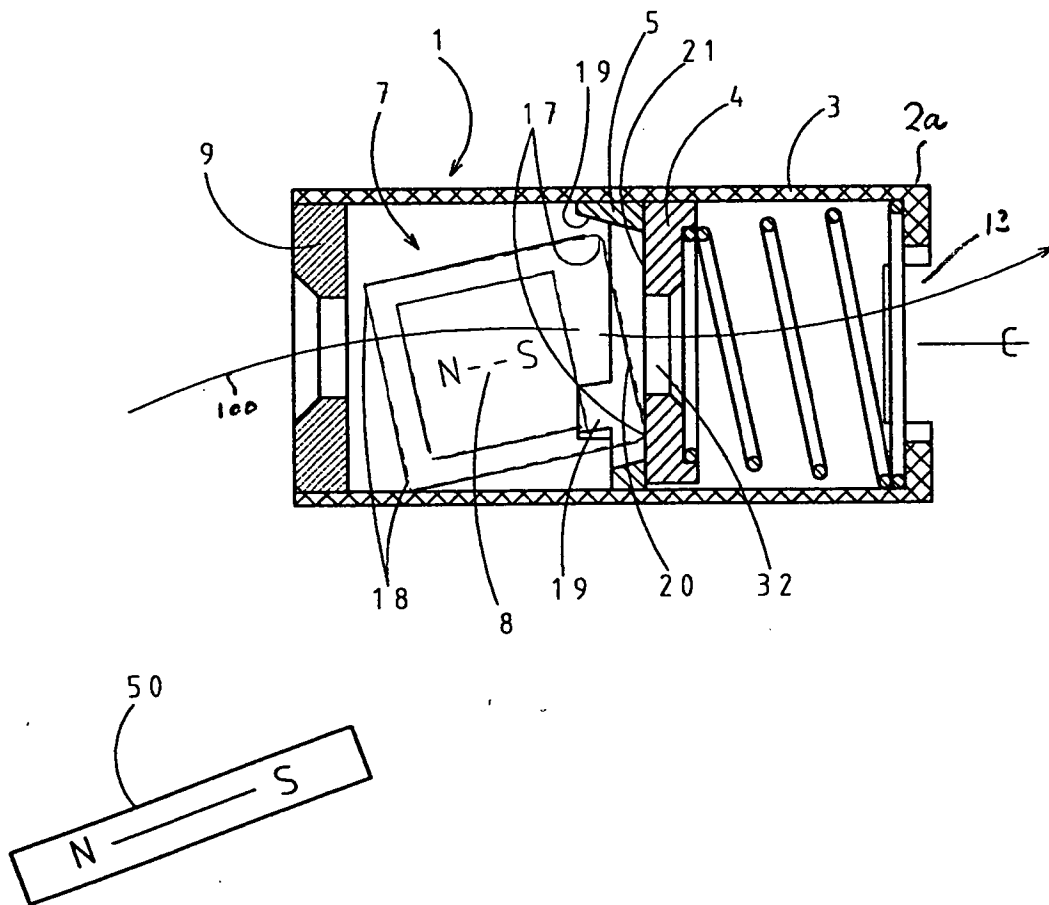


Fig 3

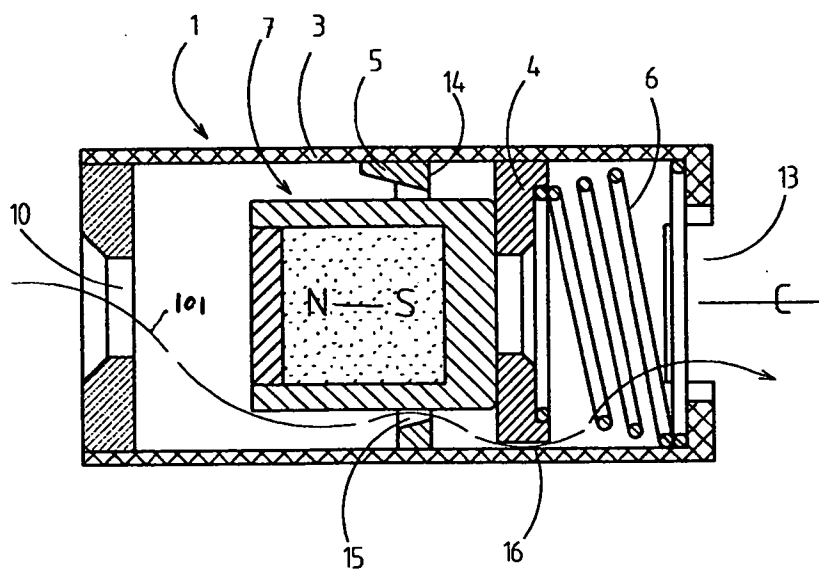


Fig. 4A

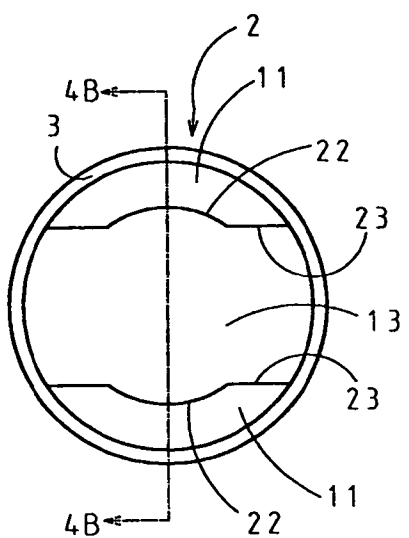


Fig. 4B

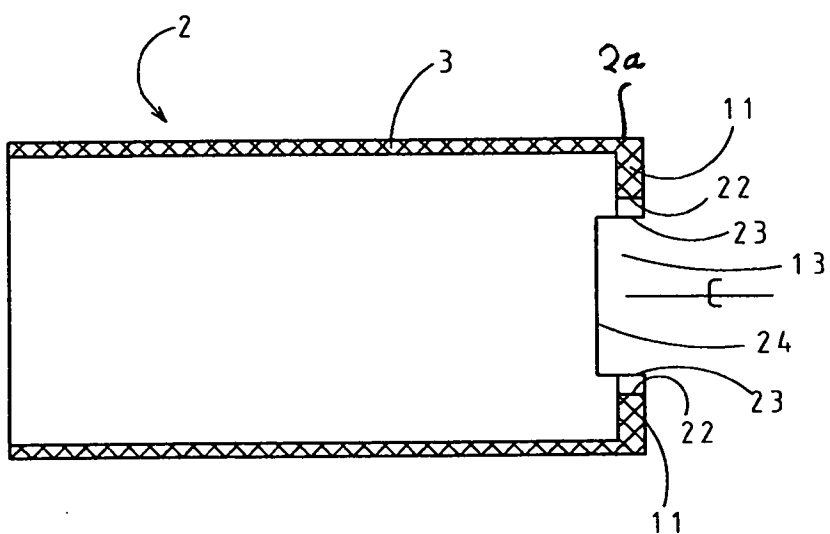


Fig 5A

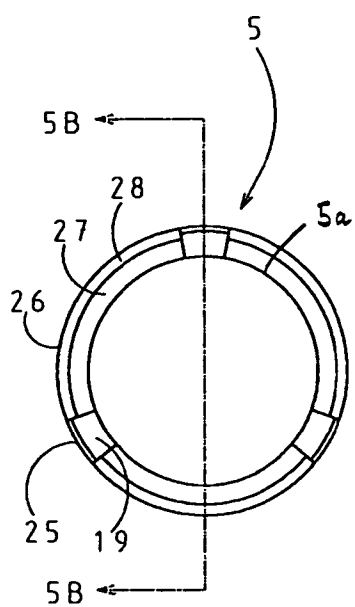


Fig 5B

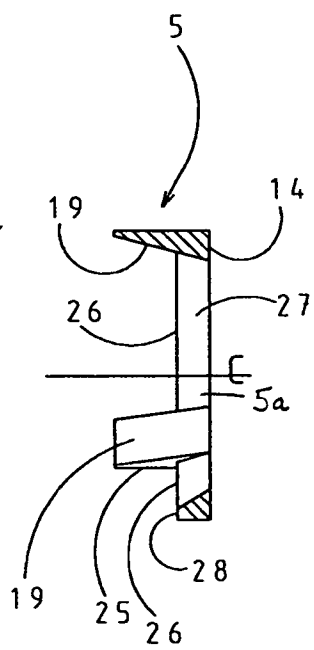


Fig 5C

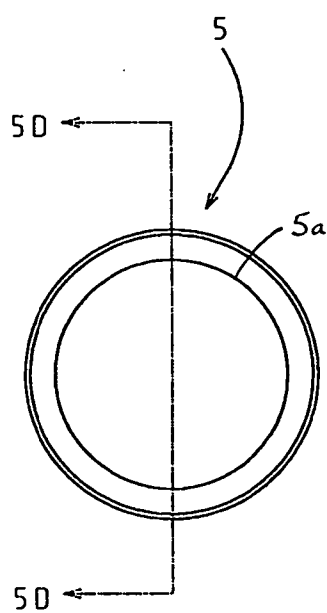


Fig 5D

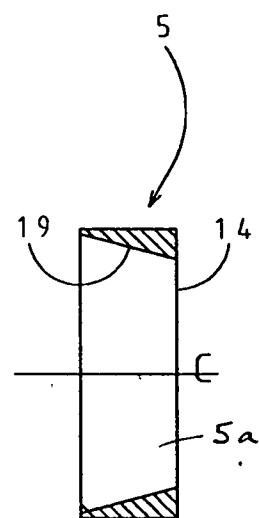


Fig. 6A

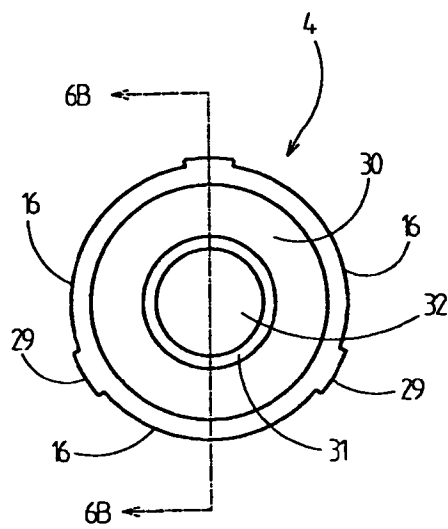


Fig. 6B

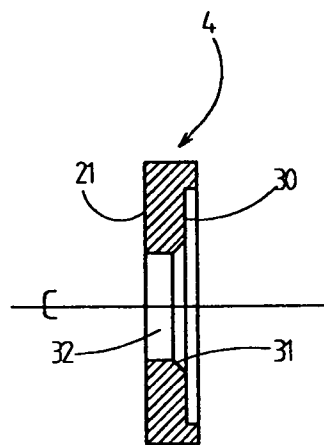


Fig. 7

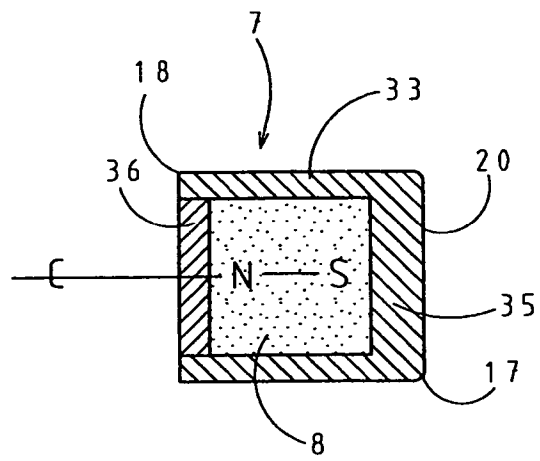
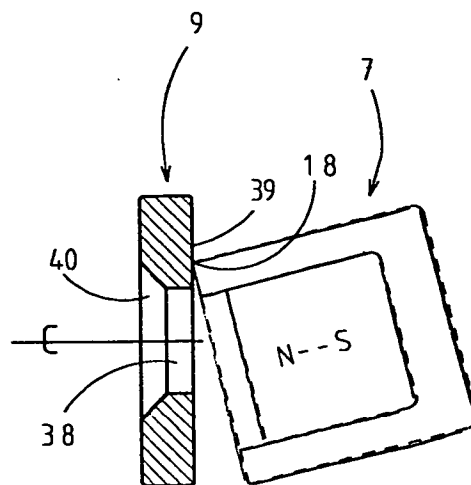


Fig. 8



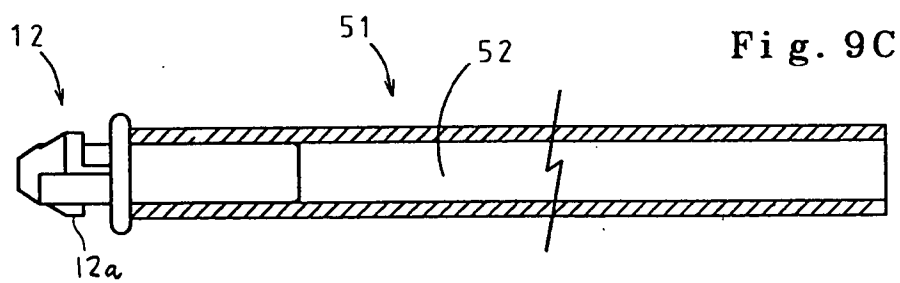
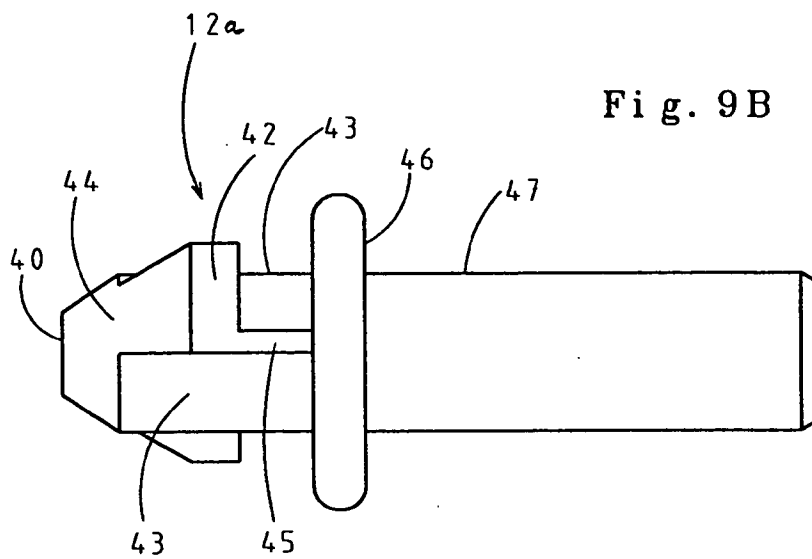
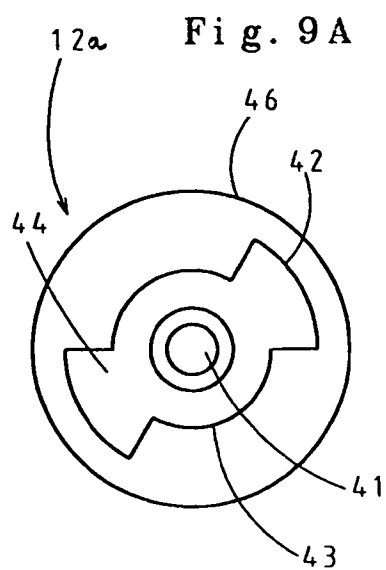


Fig. 10A

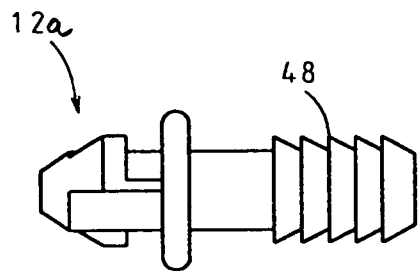


Fig. 10B

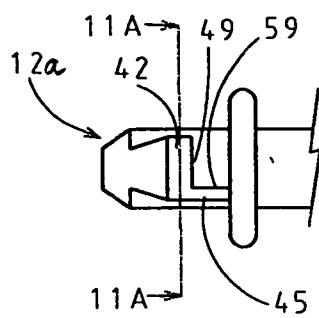


Fig. 10C

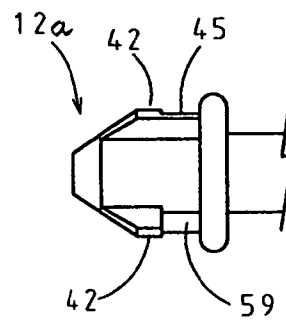


Fig. 11A

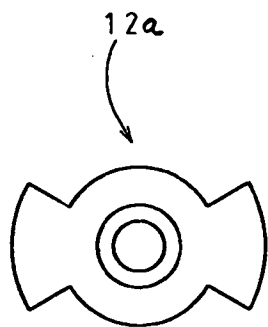


Fig. 11B

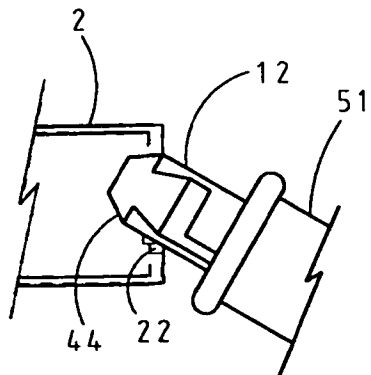
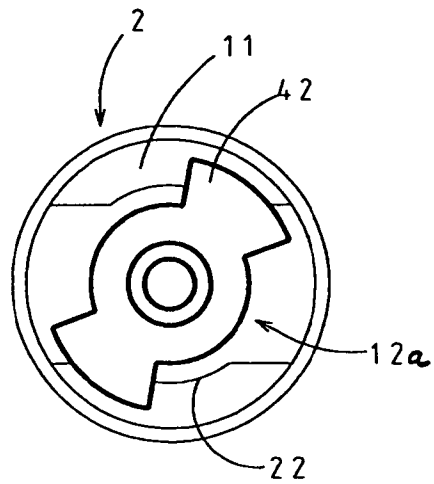
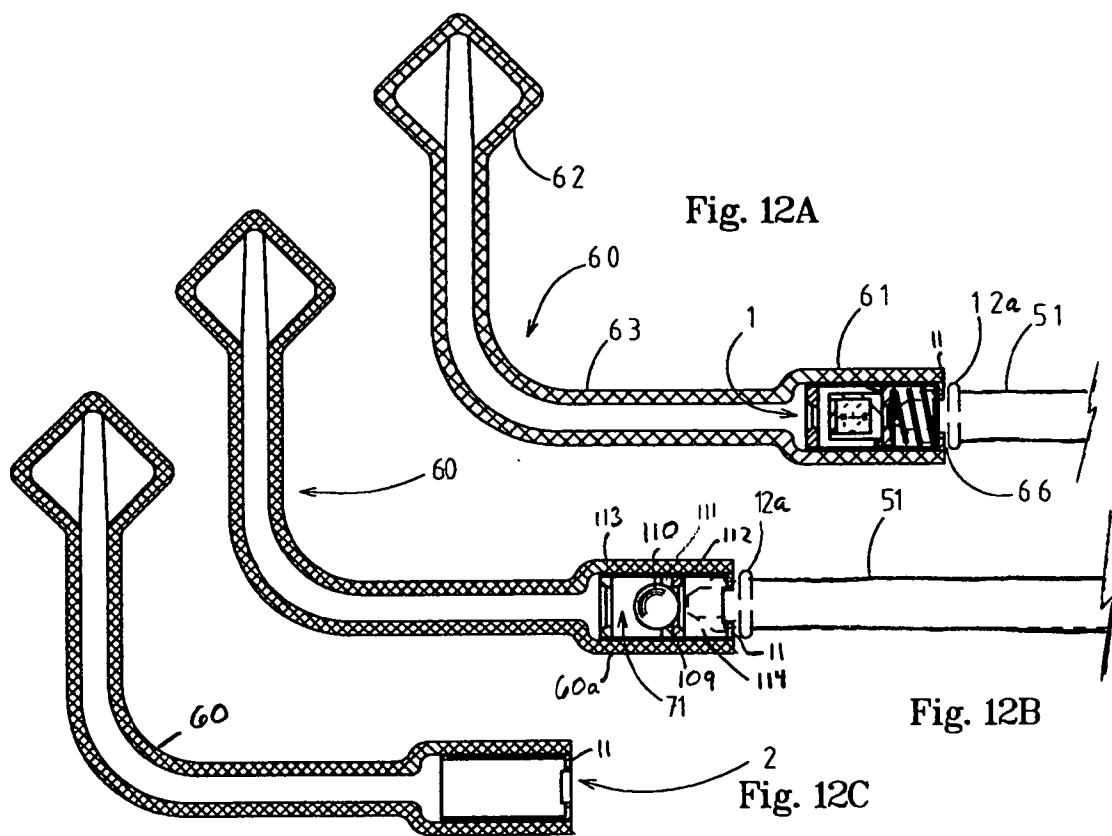


Fig. 11C



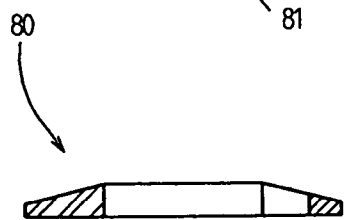
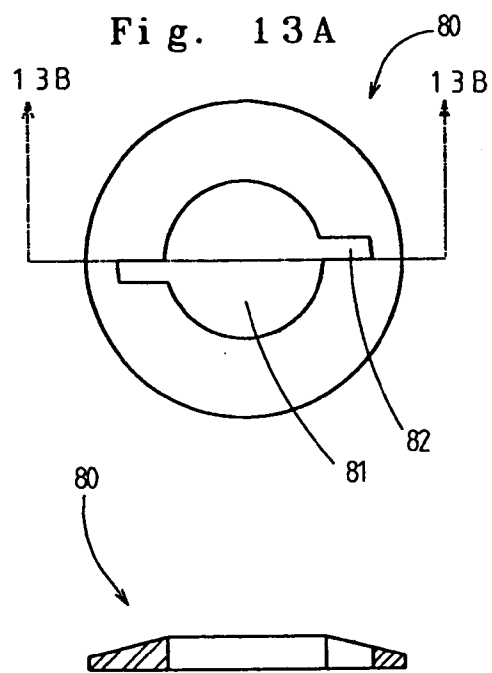


Fig. 13B

